IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

UNITED STATES OF AMERICA
***ex rel.* JOANNE HARTWIG** **PLAINTIFF**

v. **CIVIL ACTION NO. 3:11cv413-CWR-LRA**

MEDTRONIC, INC.;
MEDTRONIC SOFAMOR DANEK USA., INC.; THOMAS A. ZDEBLICK, M.D.;
TAZ CONSULTING, INC.; CURTIS A. DICKMAN, M.D.; VANTAGE CONSULTING, INC.; ADAM LEWIS, M.D.; TAZ LLC; LEWIS MEDICAL SERVICES, PLLC;
LEWIS PROPERTIES, LLC;
JACKSON NEUROSURGERY CLINIC, PLLC;
AND JOHN DOE DEFENDANTS 1-5000 **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

Before the Court is a series of motions including a Motion to Strike Amended Complaint and Motion to Stay Proceedings, Docket No. 65; and Motions to Dismiss Relator's Amended Complaint. Docket Nos. 66, 69, 72. Because other material outside the pleadings was presented to and not excluded by the Court, each of the motions to dismiss were treated as motions for summary judgment under Fed. R. Civ. P. 56. After careful consideration of the briefs, the arguments of the parties and a hearing on the motions, the motion to strike is DENIED; the motion to stay proceedings is deemed MOOT; and the Defendants' motion to dismiss the amended complaint are due to be GRANTED.

Background

A. Factual Background[1]

This case arises out of a *qui tam* action brought by relator Joanne Hartwig on behalf of

the United States ("Relator").[2] Medtronic, a company that produces medical devices, had developed products that they believed would have wide usage in spinal cord surgeries. The Relator alleges that Medtronic developed a scheme to market both its INFUSE and Pyramid products for use in contexts not approved by the U.S. Food and Drug Administration (FDA). In or about January 2002, the FDA granted Medtronic's premarket approval application for Pyramid, an "anterior plate fixation system." The FDA had limited the application of Pyramid to a certain type of spinal surgery ("the lumbrosacral level below the bifurcation of the vascular structures," or the L5-S1). Around July 2002, the FDA approved Medtronic's premarket application forI INFUSE, a series of bone graft products. The approval was limited to the application of the device from the L4-S1 levels. In addition, the FDA required Medtronic to conduct certain studies and testing before releasing INFUSE on the market.

Dr. Thomas Zdeblick, an orthopedic surgeon and professor at the University of Wisconsin, invented LT-CAGE, the only device approved to act as the delivery vehicle for the INFUSE bone graft into the body. He drafted a scholarly article about LT-CAGE and rhBMP, a bone growth protein that serves the active ingredient in Medtronic's INFUSE products. He submitted it for publication in *Spine*, the leading peer-reviewed medical magazine on issues related to the spine. U.S. Department of Health and Human Services ("HHS") regulations required that he make certain disclosures in the article, including the products' connection to Medtronic. In a "Point of View" response, Dr. John O'Brien of London raised the possibility

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[1] As will be explained more fully below, the recitation of facts are the plaintiff's version and have been accepted as true.

[2] *See* 31 U.S.C. § 3730(b) (provides that persons who have evidence of fraud against the United States may assert the Government's claim on its behalf). The FCA "provides for civil suits brought by both the Attorney General and by private persons, termed relators, who serve as a *posse of ad hoc deputies to uncover and prosecute frauds against the government.*" *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 184 (5th Cir. 2009)

that there were long-term problems associated with the product and suggested that vascularization, a more simple process for fusing parts of the spine or vertebrae, might have the same level of effectiveness. According to the Relator, if O'Brien's alternative proved to be equivalent or better, it would render Zdeblick and Medtronic's INFUSE products "useless and unnecessary."

In 2002, Zdeblick became editor-in-chief of the *Journal of Spinal Disorders*. He replaced two doctors who had served as longtime co-editors of the magazine before him. He renamed the journal *Journal of Spinal Disorders and Techniques* ("JSDT") and repurposed the journal from publishing only scientific articles with strict oversight to articles with "[s]horter clinical follow-up" and technical descriptions about new techniques for clinicians in practice. In October 2002, under Zdeblick's leadership, the journal published an article co-authored in part by Dr. Curtis Dickman, who had developed the Pyramid plate and who was supported financially by Medtronic. Dickman had assisted in the approval process for INFUSE. Dickman had also submitted a letter to an FDA advisory panel in which he represented the importance of approving BMP, the key ingredient in INFUSE. The October 2002 article on INFUSE failed to disclose the authors' financial ties to Medtronic, despite industry standards requiring such acknowledgment.

The Relator claims that Medtronic made designs to have its INFUSE product supplant the use of the gold standard procedure for spinal bone grafts—the use of autogenous bone, or bone taken from the patient's hip—and they used fraudulent statements and Federal funds to do so. The JSDT published the article touting INFUSE as the new gold standard; the article failed to disclose the ties to Medtronic, Zdeblick's financial interest in the product, and the possible complications. It did not engage or counter any comparative studies using simple plaster of

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(internal quotation marks omitted) (emphasis added).

Paris, as suggested by Dr. O'Brien. In a second article, Zdeblick touted the use of LT-CAGE, his specific invention and companion to INFUSE, and rhBMP-2. That article, Hartwig alleges, also failed to disclose the connection to Medtronic and served as a "covert advertisement" for the product. The article acknowledged Medtronic Sofamor Danek "for their help in data collection and statistical analyses," but did not reveal Medtronic's ties or direct financial interests to the "monumental" conclusions in the article.

The Relator argues that failure to report these "clear conflicts of interests on the part of those holding positions of trust both within the medical community and over patients was part of the Defendants' fraudulent enterprise. . . . [U]nchecked by appropriate peer-review, the Defendants were able to systemically accomplish their goals."

In 2002, around the time Zdeblick took over JSDT and the FDA's approval of Medtronic's premarket applications for INFUSE and Pyramid, Relator Hartwig's doctor, Dr. Adam Lewis, opened his practice under a series of new names in Mississippi. After a spinal cord surgery that resulted in complications, Hartwig filed a medical malpractice suit against Dr. Lewis; a jury found in her favor and awarded compensatory damages in May 2011. During discovery in that case, the Relator contends that Lewis lied about his financial interest with Medtronic. During the trial, he disclosed that he knew and had worked with Dickman on the development of the Medtronic Pyramid plate. In discovery in a separate civil action in federal district court in Texas, Medtronic admitted that Dr. Lewis had served as a consultant on the Pyramid plate.[3] The Relator argues that Medtronic's conduct violates the federal anti-kickback law, particularly its prohibition against physicians' use of products in which Medtronic pays them royalties.

The Relator argues that Dr. Lewis and the defendants experimented on their patients by using the Pyramid plate and INFUSE products without advising the patients or gaining their informed consent. The goals were: 1) to cover for sham agreements, in which information gathered from using Medtronic products on their patients could be "passed off as justification for the Defendant physicians' real contributions." (e.g. Medtronic paid $23 million to Zdeblick for INFUSE, but used the information gathered from Zdeblick's contracting doctors, including Lewis, to justify payment for a different product); and 2) to perform unauthorized uses of Medtronic products on human subjects without their consent to expand their approved use by showing successful "off-label" uses. Defendants expanded the Pyramid plate's use from L5-S1 only in 2002 to a higher number in 2007, under the name of Pyramid +4.

Hartwig testified in her medical malpractice suit that Dr. Lewis told her that her 2005 surgery would be like her 2001 surgery on a similar part of her spine. She contends that Lewis used a Pyramid plate at L3-L4 at a time when that practice was an off-label use. He then reported his "successful experience" with this off-label use (despite a lawsuit that eventually resulted in a verdict for Hartwig). In turn, Dickman and Zdeblick were paid by Medtronic for "consulting/research."

Overall, Relator Hartwig's complaint outlines a "scheme to launder payments" from Medtronic to Dr. Lewis, via Dr. Dickman and Dr. Zdeblick. Am. Compl. ¶¶ 69, 79, 83, 86. The alleged connection appears to be the existence of a Mississippi corporation with the same business address as Dr. Lewis that also happens to have the same initials as Dr. Zdeblick. Compl. ¶ 86. Elsewhere in her complaint, however, the Relator identifies two different occasions during discovery and at her medical malpractice trial where Dr. Lewis testified that he had never

[3] *See* Docket No. 61, at 18.

received funds from Medtronic. Am. Compl. ¶¶ 60–62. In addition, Medtronic's online disclosure of payments to physicians does not report any payments to Dr. Lewis either. Am. Compl. ¶¶ 81–82. The Relator alleges that Medtronic violated the False Claims Act ("FCA") (31 U.S.C. §§ 3729(a)(1), (a)(2), and (a)(3) (2006)) by allegedly conspiring with the physician defendants to disseminate favorable peer-reviewed journal articles regarding INFUSE and to perform experimental procedures with the Pyramid Plate. Am. Compl. ¶¶ 30–58, 66. The Relator also asserts that Medtronic paid kickbacks to the physician defendants which resulted in false claims for payment through false certifications of compliance with the AKS. Am. Compl. ¶¶ 57–58, 65, 67, 69–70, 76, 78–87, 90, 92.

The counts in the amended complaint are as follows:

Counts I-III: Violations of the False Claims Act, 31 U.S.C. § 3729 *et seq*.
Count IV: Violations of 42 U.S.C. § 1320a-7b (provisions governing required disclosures for federal and state health care programs)
Count V: "Civil Penalties or Awards Arising from Criminal Conduct . . . including but not limited to those relative to 18 U.S.C. §§ 1341, 1342, 1352, 1356, and 1357, covering Mail Fraud, Wire Fraud, Travel to Effect the Scheme, Money Laundering, and Use of Dirty Money, to effectuate the fraudulent scheme."
Count VI: Violations of 45 C.F.R. 46 *et seq*. (the "Common Rule")
Count VII: Violations of Settlement Agreement Between Medtronic and HHS
Count VIII: Unjust Enrichment

B. Procedural History

On July 8, 2011, Hartwig filed a complaint against the following defendants: 1) Medtronic and its related entities (Medtronic Sofamor Danek USA, Inc.; Medtronic, Inc.) (collectively "Medtronic"); 2) Dr. Thomas A. Zdeblick and his related entities (Thomas A. Zdeblick, individually; TAZ Consulting, Inc.) (collectively, "Zdeblick"); 3) Dr. Adam Lewis and his related entities (Adam Lewis, individually; Lewis Medical Services, PLLC; Lewis Properties, LLC; TAZ, LLC; Jackson Neurosurgery Clinic, PLLC) (collectively, "Lewis"); 4) Dr. Curtis A.

Dickman (Curtis A. Dickman, individually; Vantage Consulting, Inc.) (collectively, "Dickman") and 5) John Doe Defendants 1-5000.[4] Docket No. 1. The United States declined to intervene in the action. Docket No. 8. The Lewis defendants filed an answer to the complaint on September 25, 2012. Docket Nos. 22-23. On November 26, 2012, Dickman, Zdeblick, and Medtronic all filed motions to dismiss the original complaint. Docket Nos. 44, 45, 48. Zdeblick and Dickman joined in Medtronic's motion and memorandum. Docket Nos. 50, 51. Lewis also joined in the motions filed by all three of the other defendants. Dockets No. 56, 57, 58. On December 18, 2012, the Relator filed a Second Amended Complaint. Docket No. 61. Lewis moved to strike the amended complaint or stay proceedings. Docket. No. 65.[5] Each of the Defendants moved to dismiss the Second Amended Complaint. Dockets No. 66, 68, 69, 72.[6] Dickman and Lewis joined in Medtronic's motion to dismiss and memorandum. Docket No. 74, 76. Lewis also joined in Zdeblick's motion and memorandum. Docket No. 75. The Relator filed a response in opposition to Medtronic's motion to dismiss the amended complaint. Docket No. 81. Dickman, Lewis, and Medtronic filed replies in support of their motions to dismiss. Docket Nos. 83, 84, 86, respectively. The Defendants also joined in Medtronic's reply to the Relator's response, Docket Nos. 87, 88, 90, and Dickman joined in Lewis's reply. Docket No. 89.

In the Relator's amended complaint, she effectively seeks to cure deficiencies in the original complaint. For the reasons below, the Defendants are entitled to a judgment as a matter of law.

Legal Standards

A. Rule 56 Standard

[4] In the Second Amended Complaint, Relator removed John Doe Defendants 1-5000. Docket No. 61.
[5] The Relator responded to Lewis's motion to strike or stay proceedings. Docket No. 77.

"[A] challenge under the FCA jurisdictional bar is necessarily intertwined with the merits and is, therefore, properly treated as a motion for summary judgment." *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 173 (5th Cir. 2004) (citation and internal quotation marks omitted). When considering a motion to dismiss for failure to state a claim upon which relief can be granted, if "matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." *Fed. R. Civ. P. 12(d).* Summary judgment is only proper when the record indicates that there is not a "genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Fed. R. Civ. P. 56.* A genuine issue of fact exists only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986); *see also Taita Chem. Co., Ltd. v. Westlake Styrene Corp.*, 246 F.3d 377, 385 (5th Cir. 2001). When considering a motion for summary judgment, this Court "will review the facts drawing all inferences most favorable to the party opposing the motion." *Reid v. State Farm Mut. Auto. Ins. Co.*, 784 F.2d 577, 578 (5th Cir. 1986).

The party moving for summary judgment bears the initial burden of "informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party has met its initial burden, however, "the burden shifts to the non-moving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial." *Engstrom v. First Nat'l Bank of Eagle Lake*, 47 F.3d 1459, 1462 (5th Cir. 1995). In order to satisfy its burden, the non-moving party must put forth

[6] Lewis joined in the motion to dismiss the amended complaint filed by Dickman. Docket No. 68.

competent evidence and cannot rely on "unsubstantiated assertions" and "conclusory allegations." *See Lujan v. Nat'l. Wildlife Fed'n*, 497 U.S. 871, 888 (1990); *RSR Corp. v. Int'l Ins. Co.*, 612 F.3d 851, 857 (5th Cir. 2010).

B. Rule 9(b) Standard

"[A] complaint filed under the False Claims Act must meet the heightened pleading standard of Rule 9(b), which provides: 'In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.'" *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009) (quoting Fed. R. Civ. P. 9(b)) (footnote omitted). Whereas Rule 9(b) generally requires a plaintiff to plead the "time, place and contents of a false representation, as well as the identity of the person making the misrepresentation and what that person obtained thereby, the Fifth Circuit has held that this standard is not a straitjacket." *United States ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 533 (N.D. Tex. 2012) (citing *Grubbs*, 565 F.3d at 186, 190) (quotation marks omitted). Therefore, in the context of a claim under the FCA presentment provision, "which makes liable any person who 'knowingly presents, or causes to be presented' a false claim to the Government," *Grubbs*, 565 F.3d at 188 (quoting 31 U.S.C. § 3729(a)(1)), "a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id*. at 190.

Lastly, "[t]he particularity requirements of Rule 9(b) apply to the [FCA's] conspiracy provision with equal force as to its 'presentment' and 'record' provisions." *Id*. at 193. Therefore, in order to sustain a claim for conspiracy to commit fraud, the relator must "plead

with particularity the conspiracy as well as the overt acts . . . taken in furtherance of the conspiracy." *Id*. (citation omitted).

Analysis

I. Motion to Strike Amended Complaint

As an initial matter, the Court will address the motion to strike the amended complaint filed by Defendant Lewis. Docket No. 65. Rule 15 provides for amendment (1) as a matter of course, and (2) with consent or leave, stating in pertinent part:

> (1) *Amending as a Matter of Course.* A party may amend its pleading once as a matter of course within:
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> (A) 21 days after serving it, or
> (B) if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b) , (e) , or (f) , whichever is earlier.
>
> (2) *Other Amendments.* In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires.

Fed. R. Civ. P. 15(a)(1-2). Lewis argues that the Court should strike the amended complaint for two reasons: the Relator was not allowed to amend as a matter of course under the plain reading of Rule 15; the last day to file the amended complaint would have been October 1, 2012—21 days after the last defendant was served with process—and the Relator filed the amended complaint on December 18, 2012, after the required date; and because it was filed without the opposing party's written consent and without leave of court, in violation of Federal Rule of Civil Procedure 15(a)(2).[7] The Relator replies that Lewis has not shown that the amended complaint

[7] On the alternative motion to stay, Lewis also requested that, if the Court strikes the amended complaint, that the Court issue an order staying any attorney conferences, disclosure requirements, and all discovery pursuant to Local Rule 16(b)(3)(B) to save resources for the parties and the Court. In his reply to Relator's response, however, Lewis admits that the relief of the stay requested has already been addressed and granted in part by this Court, in

did not fall within the purview of Rule 15(a)'s allowance of amendment as a matter of course.

It is important to note that "[a] motion to strike is considered an exceptional remedy and is generally disfavored, and the proponent of such a motion must shoulder a formidable burden." *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 34-35 (D.D.C. 2007) (internal citation omitted). In fact, Federal Rule 15(a)(2) provides that leave to amend should be freely granted "when justice so requires." Although the Court recognizes that the Relator failed to obtain leave of court before filing her amended complaint, Lewis has not demonstrated any showing of prejudice as the result of the Relator's failure to obtain leave of court in order to file the amended complaint following Defendants' motions to dismiss the initial complaint.

In this case, there is no substantial difference between the second and first amended complaint. As the Fifth Circuit recognized in a similar case, a court may consider an amended complaint filed without leave of court where it is "more procedurally expedient to consider the complaint filed than to strike the amended complaint and then grant leave to file another complaint that raised the exact same issues. And more important, the parties would be in the same position regardless of which procedure the court used." *United States ex rel. Mathews v. HealthSouth Corp.*, 332 F.3d 293, 296-97 (5th Cir. 2003).[8] Additionally, all the parties in this

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that "[d]iscovery has been stayed except with respect to any discovery needed regarding jurisdictional issues." Docket No. 79, at 3. Thus, it appears that he would no longer like to pursue it, rendering this motion moot.

[8] For this proposition, the Fifth Circuit cited *Hicks v. Resolution Trust Corp.*, 767 F. Supp. 167, 170 (N.D. Ill. 1991), in which the court considered the amended complaint filed even though the Relator never requested leave because the complaint "merely alleged additional theories of liability based on the same set of facts," which the court would have allowed the Relator to re-file. Similarly, in this case, the Defendants have recognized that the amended complaint is not very different from the original complaint. *See* Medtronic Reply to MTD, Docket No. 73, at 1 (indicating that Relator filed an amended complaint, "adding six paragraphs to the original, 114-paragraph, complaint, deleting six paragraphs, and making inconsequential modifications to 24 other paragraphs" (citing Declaration of Michael J. Vito, Docket No. 72, Ex. 1 (Redline of Complaint against Amended Complaint)). In fact, Lewis joined in that memorandum, Docket No. 76, along with the other Defendants, but none of the other

case have treated the motions to dismiss as properly in issue. Both of these reasons support a denial of the motion to strike. *See Georgia Power Project v. Georgia Power Co.*, 409 F. Supp. 332, 336-37 (N.D. Ga. 1975). Retaining the amended complaint also supports the underlying principles of Rule 15, and in this case, furthers the progress of the litigation. *See Allstate Life Ins. Co. v. Estate of Reed*, No. 1:05CV164-LG, 2007 WL 1040507, at *6 (S.D. Miss. Mar. 30, 2007) (accepting amended pleading filed without leave of court under the circumstances "in the interest of judicial economy"), *aff'd sub nom. Allstate Life Ins. Co. v. Parnell*, 292 F. App'x 264 (5th Cir. 2008); Wright, Miller & Kane, *Federal Practice and Procedure* § 1484 (1990) ("Permitting an amendment without formal application to the court under these circumstances is in keeping with the overall liberal amendment policy of Rule 15(a) and the general desirability of minimizing needless formalities."). Thus, the Court will consider the amended complaint as filed.

II. Claims Against Medtronic/All Defendants[9]

Under the False Claims Act, Title 31 U.S.C. §3729, *et seq*., civil liability lies against any person who "(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or] (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid . . . ." *See* 31 U.S.C. §3729(a);

Defendants joined in this motion to strike. In a status conference, the parties also agreed that "the *Amended* Complaint and the motions related thereto are the relevant pleadings for the Court to consider." Text-Only Order, Sept. 17, 2013 (emphasis added).

[9] During the litigation, Medtronic's motion to dismiss and responsive pleadings thereafter have served as the main source of all of the Defendants' arguments, as indicated by the Defendants' joinder in each of Medtronic's filings on the motion. Accordingly, the Court will first consider Medtronic's arguments and address the specific

Grubbs, 565 F.3d 180, 193 (5th Cir. 2009). For the reasons stated below, the Relator has not established that there is a genuine issue of material fact as to whether the Defendants submitted false claims under the FCA.

A. Subject Matter Jurisdiction

Defendants have argued that the Court lacks subject matter jurisdiction over the Relator's *qui tam* action under the FCA because the allegations in the complaint are based upon previously disclosed information. The Defendants allege that, well before the Relator filed her complaint, the government was already aware of allegations concerning Medtronic's promotion of its INFUSE and Pyramid products and its collaboration with physician-consultants. The Court agrees.

The FCA's public disclosure bar provides that "[n]o court shall have jurisdiction over an [FCA *qui tam*] action . . . based upon the public disclosure of allegations or transactions in a . . . criminal, civil, or administrative hearing, in a congressional, administrative . . . report, hearing, audit, or investigation, or from the news media, unless . . . the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A).[10] This jurisdictional inquiry requires courts to consider three questions: "(1) whether there has been a 'public disclosure' of allegations or transactions, (2) whether the *qui tam* action is 'based upon' such publicly disclosed allegations, and (3) if so, whether the relator is the 'original source' of the information." *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 450 (5th Cir. 1995). The purpose of this

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arguments of other Defendants who have filed separate pleadings where they are relevant and require additional analysis.

[10] The public disclosure bar was amended by the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 901, signed into law on March 23, 2010. The amendments are irrelevant here because they do not apply retroactively to alleged false claims made before March 23, 2010, and Relator has not identified any claims occurring after that date. *United States ex rel. Osheroff v. Humana, Inc.*, No. 10-24486-cv, 2012 WL 4479072, at *4

jurisdictional bar is to accommodate the primary goals of the False Claims Act: (1) "promoting private citizen involvement in exposing fraud against the government" and (2) "preventing parasitic suits by opportunistic late-comers who add nothing to the exposure of fraud." *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 176 (5th Cir. 2004).

1. Previously Disclosed Information

Under 31 U.S.C. § 3730(e)(4), the Court must first consider "whether there has been a 'public disclosure' of allegations or transactions." *Id*. The "public disclosure" jurisdictional bar applies where the allegations have been disclosed in "a criminal, civil, or administrative hearing, in a congressional, administrative, or government accounting office report, hearing audit, or investigations, or from the news media." The Relator's claims are as follows: 1) improper collaboration between defendants to increase use (including off-label use) of INFUSE and Pyramid Plate through the drafting of certain peer-reviewed publications; 2) Medtronic paid kickbacks to the physician defendants which resulted in false claims for payment through false certifications of compliance with the AKS; 3) Dr. Lewis and other physician defendants performed surgeries on patients as "experimentation" without "informed consent"; and 4) the Defendants entered into a "fraudulent enterprise and civil conspiracy" to submit a variety of "false records."[11]

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n.8 (S.D. Fla. Sept. 28, 2012) (citing *Graham Cnty.*, 130 S. Ct. at 1400 n.1).

[11] "Those false records included, but were not limited to: (a) false records generated for reimbursement of medical services for surgeries and related care; (b) false records generated for reimbursement of Medtronic products; (c) false records generated to conceal the fraudulent scheme to maintain the appearance of compliance with Anti-Kickback laws and regulations; (d) false records generated in order to launder money in an effort to facilitate the fraudulent scheme to maintain the appearance of compliance with Anti-Kickback laws and regulations; (e) false records intended to defraud the Office of the Inspector General into believing Medtronic was in compliance with the provisions of the Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Medtronic Sofamor Danek USA, Inc., entered into as part of a settlement of other

In this case, Medtronic argues that the Relator's actions have been publicly disclosed in the following ways: (a) an investigation by the U.S. Department of Justice related to INFUSE, which was widely reported in the press and was the focus of a securities class action lawsuit; (b) a Congressional inquiry into, among other things, financial ties between Medtronic and physicians who use INFUSE and communication with physicians about INFUSE clinical research, which was also publicly reported; (c) press reports that specifically focused on the relationship between Dr. Zdeblick and Medtronic; and perhaps most importantly, (d) prior *qui tam* litigation. *See* Docket No. 49, at 13-14.

According to the record, nearly ten years before the Relator filed her complaint, the United States intervened in an earlier *qui tam* action that alleged, in part, "that Medtronic paid physicians to encourage the use of INFUSE for off-label purposes." *See United States ex rel. Doe v. Medtronic*, No. 02–2709 (W.D. Tenn. 2002). In July 2006, Medtronic settled claims arising from the *Doe* complaint including claims arising from "payments made pursuant to consulting, royalty, fellowship and research agreements with" a number of physicians (including Dr. Zdeblick) from January 1, 1998 to April 1, 2003, a period that covers his authorship of the three articles described in the instant complaint. Docket No. 48, Caffrey Decl. Ex. 16 at 2 (2006 Settlement Agreement). In addition, a second *qui tam* action raised the same allegations as the *Doe* complaint and was dismissed in connection with the government's settlement of *Doe*. *See U.S. ex rel. Poteet v. Medtronic*, 552 F.3d 503 (6th Cir. 2009). Finally, a third *qui tam* action ("Poteet II") alleged that 120 spine surgeons and 18 medical device distributors committed violations of the FCA by accepting kickbacks from Medtronic. *Id.*, Caffrey Decl. Ex. 17 (U.S. ex rel. Poteet v. Lenke Complaint). The court dismissed this third complaint in March 2009,

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claims; (f) and others." Am. Compl. ¶ 98.

reasoning that its allegations were jurisdictionally barred because of prior public disclosure of the allegations. *Id.*, Caffrey Decl. Ex. 18 at 4, 7 (*Poteet II* Opinion).

"An FCA *qui tam* action even partly based upon public allegations or transactions is nonetheless based upon such allegations or transactions" and should be dismissed. *Reagan*, 384 F.3d at 176 (quotation marks omitted); 31 U.S.C. § 3730(e)(4)(B). A public disclosure occurs when the "essential elements" of the allegedly fraudulent transaction are released into the public domain. *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 377 (5th Cir. 2009). Every fact supporting a relator's allegations need not be publicly disclosed, as long as there is enough information to "alert[] the government to . . . the fraud." *United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 329 (5th Cir. 2011) (quotation marks omitted). Disclosures that create an "inference of fraud," which can be drawn from facts revealed in different sources, are sufficient. *United States ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 519 (N.D. Tex. 2012) (quotation marks omitted). A *qui tam* action is "based upon" public disclosures if the allegations in the complaint are "the same as or substantially similar to those that have been disclosed" publicly. *United States ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 673, 683 (W.D. Tex. 2006). If the complaint "repeats what the public already knows, regardless of whether or not Relators learned about the fraud independent of the public disclosures," it is still considered "based upon" the public disclosures. *Id.* Similarly, "providing more specific details about what happened does not change the fact that [relator's] allegation is substantially similar to and therefore 'based upon' the publicly disclosed allegations." *United States ex rel. Davis v. District of Columbia*, 679 F.3d 832, 837 (D.C. Cir. 2012) (internal quotation marks omitted)).

As for the prior *qui tam* litigation, it is well settled that "any information disclosed through civil litigation and on file with the clerk's office should be considered a public disclosure of allegations in a civil hearing for purposes of section 3730(e)(4)(A)." *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 450 (5th Cir. 1995) (quotation marks omitted)). Statements made to the FDA are sufficient to put the government on notice of potential fraud. *See, e.g.*, *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005). Work in medical journals is also covered by the public disclosure bar. *See Colquitt*, 864 F. Supp. 2d at 518 (applying the term "news media" as used in the False Claims Act statute to "scholarly, scientific, and technical periodicals") (citations omitted). These disclosures fit squarely within the FCA's specified public sources. 31 U.S.C. § 3730(e)(4)(A) (enumerating administrative hearings, reports, or investigations and news media); *see also United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App'x 244, 256 (4th Cir. 2012) ("[D]ocuments created by private parties constitut[e] materials of 'administrative hearings' for the FCA . . . can also constitute an administrative report" including privately-created SEC filings); *United States ex rel. Repko v. Guthrie Clinic, P.C.*, 490 F. App'x 502, 504 (3d Cir. 2012) (characterizing website content as a "public disclosure of information").

All of the key allegations the Relator's amended complaint are based on publicly available information. The Relator's INFUSE-related publication allegations are premised upon facts from newspaper articles, Senate Finance Committee investigation letters, FDA submissions, prior *qui tam* litigation, and peer-reviewed medical journals. Am. Compl. ¶¶ 24–40, 42–55, 57, 77, 80. The Relator's Pyramid Plate allegations also rely on the information from prior *qui tam* litigation, supplemented by further publicly disclosed information. The Relator's

allegations involving Drs. Lewis, Zdeblick and Dickman, along with their relationship to Medtronic and each other, have come from administrative filings with the Mississippi Secretary of State and content on Medtronic's physician relationships website. In its response, the Relator has provided a policy argument, suggesting that the Defendants have unduly broadened the application of the public disclosure bar to include "public information" contained in the Relator's complaint instead of limiting the bar to publicly disclosed "allegations or transactions." The Relator has not disputed that its allegations or the transactions that it has described are largely based on previously disclosed, or public, information for the purposes of applying the FCA public disclosure bar. The "essential elements" of the Relator's claims here were in the public domain years before she filed her complaint. *See Branch Consultants*, 560 F.3d at 377. Thus, those allegations are barred under the public disclosure rule.

2. Original Source

If an FCA complaint is based upon public disclosures, the action is jurisdictionally barred unless the relator establishes that she is an original source. 31 U.S.C. § 3730(e)(4)(A). To qualify as an original source, the Relator must "possess direct and independent knowledge of the information on which the publicly disclosed allegations are based." *Reagan*, 384 F.3d at 177 (quotation marks omitted). *See also United States ex rel. Woods v. SouthernCare, Inc.*, 3:09cv313, 2013 WL 5445239, at *1 (S.D. Miss. Sept. 30, 2013). The Relator's allegations related to INFUSE and Pyramid products are derived entirely from public disclosures.

In her amended complaint, at Docket No. 61, the Relator has added specific details about her treatment from Dr. Lewis. These amendments before filing her answer to the initial motions to dismiss suggest that her response to this defense is that she is the "original source" of

information in this action because the treatment from Dr. Lewis was received by her personally. The Relator's recitation of Dr. Lewis's alleged statements to her regarding the procedure that formed the basis of her malpractice action, Am. Compl. ¶¶ 66, 69, cannot form the basis of an FCA claim, as they do nothing to establish her personal knowledge regarding the submission of any false claim. Her claims are still subsumed within the same underlying theory of unapproved promotion and sales alleged in prior complaints. *See, e.g.*, *Branch Consultants*, 560 F.3d at 378 (relator cannot avoid the first-to-file bar "by simply adding factual details or geographic locations to the essential or material elements of a fraud claim against the same defendant described in a prior compl[ai]nt"). The Relator provided a conclusory allegation that she is the "original source" of the information, relying on the public disclosures cited above. In her response, she has not refuted these arguments or indicated that she is the original source of any specific claim that would be entitled to survive the motion to dismiss. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 476 (2007) (holding that the fact that public disclosure bar and whether relator is an original source must be analyzed on a claim-by-claim basis). Without direct and independent knowledge, the Relator is not an original source. Thus, the Court lacks subject matter jurisdiction under the public disclosure bar and the Defendants are entitled to judgment as a matter of law.

Even assuming that the Court does have subject matter jurisdiction, the complaint is due to be dismissed for the following reasons below.

B. Failure to State A Claim (Rule 12(b)(6))

The Relator appears to advance three general theories of FCA liability: (1) that Medtronic collaborated with the physician defendants to disseminate favorable peer-reviewed journal

articles to "broaden the use" of INFUSE; (2) that Medtronic conspired with Dr. Lewis to perform experimental procedures with the Pyramid Plate to expand the use of that product without the patients' informed consent; and (3) that Medtronic caused false and fraudulent claims for payment to federal healthcare providers by making or causing false representations of compliance with the AKS. Am. Compl. ¶¶ 30–58, 66, 90–92. Courts have held that to properly plead a FCA complaint relator must at a minimum allege "(1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that is presented to the Government." *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010). The Relator, however, has failed to allege the most basic elements of an FCA claim.

On its face, the amended complaint sets out a series of allegations that, she says, indicate a general marketing scheme "designed to broaden the application of [INFUSE and Pyramid] by end users." Am. Compl. ¶ 17. In addition, the complaint avers in a conclusory manner that Defendants falsely certified compliance with the AKS in connection with claims for reimbursement. Am. Compl. ¶ 92. Neither allegation is sufficient, as a matter of law, to raise a plausible claim for relief. *United States ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 (5th Cir. 2008) (Relator "must state the factual basis for the fraudulent claim with particularity and cannot rely on speculation or conclusional allegations.").

1. Off-Label Use of INFUSE and Pyramid

The Relator alleges that the Defendants engaged in a "scheme" of "illegal, 'off-label' marketing" of INFUSE and Pyramid, "which was encouraged by the use of kickbacks disguised as payments for other services." These off-label uses allegedly were to expand the FDA's

approved uses for the devices. Am. Compl. ¶ 3, 68, 69, 93. As the Supreme Court has noted, "off-label use [of medical devices] is generally accepted" in medical practice, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001), and is expressly permitted under the Federal Food, Drug, and Cosmetic Act ("FDCA"), *see* 21 U.S.C. § 396 (2006). Off-label use is also not a bar to federal reimbursement. *United States ex rel. George v. Bos. Sci. Corp.*, 864 F. Supp. 2d 597, 600 (S.D. Tex. 2012) ("The FDA does not restrict hospitals from purchasing, or physicians from prescribing or using, products for off-label uses. To the contrary, off-label use of many medical devices and drugs is an accepted medical practice."). Accordingly, allegations of off-label promotion are insufficient to bring rise to FCA liability. *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 510 (S.D. Tex. 2011), *vacated in part on other grounds*, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012) ("FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the Food, Drug, & Cosmetic Act, that are independent of any false claim." (citations omitted)); *Bennett*, 2011 WL 1231577, at *29 ("[E]ven if a drug or device manufacturer's marketing or promotion activities violate FDA regulations, that is insufficient to plead that the manufacturer caused physicians or hospitals to submit false claims for reimbursement.").

2. Lack of Informed Consent

The Relator has alleged that Defendants violated the FCA because they falsely certified to Medicare and other federal health agencies that they had obtained informed consent from patients before making these off-label uses of Medtronic's products.[12] The Relator argues that

[12] The Relator alleges in pertinent part that "the Defendants have violated, or caused to be violated, a number of provisions of the United States Code, and implicating other Federal authorities, including, but not limited to: . . .

(b) 42 C.F.R. §482.13, codifying the Patient's rights to Informed Consent;

HHS would never have paid the fees requested if "payment would not have been made had the Defendants' express or implied certifications of compliance with the Anti-Kickback Statute ("AKS") and the Common Rule" been given. Relator Response to MTD Am. Compl, Docket No. 77, at 7. Defendants have argued that the Relator has not alleged that Medtronic knowingly caused the submission of a false claim.

The informed consent "scheme" that the Relator alleges cannot form the basis for FCA liability because payment of Medicare claims does not require informed consent. *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 269 (5th Cir. 2010) ("[A] false certification of compliance, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance."). "Provision of informed consent to patients, *see* 42 C.F.R. §§ 482.13, 482.51 (2012), is a condition of *participation* in Medicare enforced through administrative mechanisms, not a condition of payment considered actionable under the FCA." *United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F. Supp. 2d 972, 978 (W.D. Tenn. 2007) (conditions of participation codified at 42 C.F.R. §§ 482.1 *et seq*. "are quality of care standards directed towards an entity's continued ability to participate in the Medicare program rather than a prerequisite to a particular payment").

The Relator has argued that questions regarding conditions of payment are questions of fact, according to Fifth Circuit precedent. *See Gonzales v. Fresenius Med. Care N.A.*, 689 F.3d 470, 476 n.6 (5th Cir. 2010) (citing *United States ex rel. Thompson v. Columbia/HCA*

(c) 42 C.F.R. §482.51, covering the informed consent of surgical patients;
(d) 45 C.F.R. §46, covering the conduct of medical research on human subjects with the support of federal funds, known as the "Common Rule"; [and]
(e) 18 U.S.C. §1035 of the Criminal Code covering the making of "False Statements Relating to Health Care Matters" involving any health care benefit program, public or private; cf. 18 U.S.C. 1347 of the Criminal Code covering "Health Care Fraud" involving any health care benefit program, public or private . . . "

Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997)). The Relator contends that there is "sufficient indicia of reliability" to support her allegations. This Court disagrees. The Relator has failed to assert the existence of a false certification of compliance. *Id*. at 475. Instead, the Relator summarily concluded that "[i]n making claims for services and product reimbursement, the Defendants, and each of them, represented compliance with a material condition of payment that was not in fact met." Am. Compl. ¶ 92.

Even given that questions regarding conditions of payment are questions of fact, the Relator still bears the burden of pleading facts to show that Defendants' liability is at least plausible. *Iqbal*, 556 U.S. at 678. "[C]onclusory allegations will not suffice to prevent a motion to dismiss and neither will unwarranted deductions of fact." *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 379 (5th Cir. 2003) (quotation marks and citations omitted).

The Relator's allegation requires proof of an AKS violation to establish false certifications of the AKS. *United States ex rel. Jamison v. McKesson Corp.*, No. 2:08cv214, 2012 WL 4499136, at *11 (N.D. Miss. Sept. 28, 2012) (rejecting FCA claim premised upon AKS violation "because there was no violation of the Anti-Kickback Statute"). However, an AKS violation alone does not create a cause of action under the FCA because evidence of an actual false claim is essential to an FCA violation. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) ("[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" (citation omitted)); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996). Thus, even if there was an underlying violation of the AKS, and this Court declines to find such

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Docket No. 61, ¶ 5.

based on these facts,[13] there must still be a false claim for payment. *Harrison*, 176 F.3d at 785. The Relator's generalized allegations have been ruled insufficient to allege a false certification theory in this circuit. *See, e.g.*, *United States ex rel. Bennett v. Bos. Sci. Corp.*, No. H-07-2467, 2011 WL 1231577, at *32 (S.D. Tex. Mar. 31, 2011) (dismissing for failure to state a claim where "the relator has not alleged that the defendants caused any hospital or physician to certify compliance with the antikickback statute"). Thus, Defendants' motion to dismiss for failure to state a claim is granted.

C. Failure to Plead Fraud With Particularity (Rule 9(b))

In her response to the motions to dismiss, the Relator includes copies of bills that Dr. Adam Lewis submitted to Medicare for payment for her back surgery. Docket No. 81, Ex. 1. She contends that she has submitted "reliable indicia of [her] allegations pertinent to a fraudulent scheme." Docket No. 82, at 6. Defendants have argued that the assertions in the complaint regarding Medtronic's relationships with physicians and promotional activity are vague and that the submission of bills standing alone fails to satisfy the particularity required under Rule 9(b). This Court agrees.

An FCA complaint cannot survive a motion to dismiss without providing particular details to describe the "who, what, when, where, and how" of the fraud. *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). Despite the submission of these bills, she has not met the requirements of well-established law, which

[13] To state a claim of an AKS violation, the Relator must allege that Medtronic (1) knowingly and willfully (2) solicited or received, or offered or paid remuneration (3) in return for, or to induce, referral or program-related business. *See* 42 U.S.C. § 1320a-7b. Without facts to support such allegations, the Relator has failed to plead that the payments to physicians were intended to induce referrals and therefore her claims predicated upon an alleged AKS violation must be dismissed. *United States ex rel. Nunnally v. W. Coast Calcasieu Cameron Hosp.*, No. 2:08 CV 0371, 2012 WL 1866586, at *3 (W.D. La. May 21, 2012) (dismissing an FCA claim premised upon false certification of compliance with the AKS where the complaint failed to allege that payments "induced any improper

requires an FCA complaint to plead "*particular details of a scheme* to submit false claims paired with reliable indicia that lead to a *strong inference* that claims were actually submitted." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (emphasis added); *United States ex rel. Woods v. SouthernCare*, 3:09cv313, 2013 WL 1339375, at *3 (S.D. Miss. March 30, 2013). As for her claims against Medtronic, the Relator must plead with particularity facts detailing how Medtronic "caused the submission of false claims." *Bennett*, 2011 WL 1231577, at *29 (citing *Grubbs*, 565 F.3d at 191–92); *see also Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 534 (N.D. Tex. 2012).

The most indispensable element of an FCA violation is a false claim. *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 676 (N.D. Miss. 2011). Indeed, the Relator has not alleged that even the Medicare payment that she entered into evidence included information that proved to be false. For example, she has not alleged that Lewis requested payment for a surgery that he did not perform. *See, e.g.*, *Colquitt*, 864 F. Supp. 2d at 530 ("[L]iability under the FCA will attach only if the person making the claim to the government was not entitled to the money or property it requested."). The Medicare payment documents also make no reference to Medicare payment for either device. Thus, the Relator has not provided any indication that her physician used either product without her consent, much less that the use would make any of the defendants liable under the FCA.

Furthermore, the Relator's complaint lacks sufficient detail regarding Medtronic's involvement in the submission of claims related to the Relator's procedure and relies upon conclusory assertions about an alleged "scheme." She has failed to plead with particularity fraud

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referrals").

and the conspiracy which led to the submission of the claim. Among other things, she has failed to identify (1) any communication between Medtronic and Dr. Lewis regarding the Relator's surgery, (2) any discussions about submitting a claim for reimbursement in connection with the procedure, or (3) any payments from any Defendant to Dr. Lewis, much less ones that violate the AKS. In the amended complaint, the Relator alleged that INFUSE and Pyramid were used in her surgery, *see* Am. Compl. ¶ 66, but she has not identified any instances in which Medtronic generally promoted the use of INFUSE for use with the Pyramid Plate or specifically discussed INFUSE with Dr. Lewis. Thus, the Relator has not connected the dots between Medtronic and any false claim submitted to the government – which is necessary to state a claim.

1. Lewis Defendants

The Lewis Defendants filed a separate reply to the Relator's response in which they state that Dr. Lewis has "no personal financial or pecuniary relationship nor has he received any money from the Medtronic Defendants, Zbedlick [sic] Defendants or Dickman Defendants" and that "[a]ny payments received from Medicare were for services rendered to her and were not knowingly fraudulent or false." Docket No. 85, at 5. As for Dr. Lewis and Jackson Neurosurgery, who were directly implicated in the Medicare bill submitted by the Relator, the Relator has provided disparate facts that do not meet the standard in *Grubbs*, which governs motions to dismiss under Rule 9(b) for FCA claims.

Grubbs involved a healthcare provider who had allegedly submitted false claims for payment. The relator (1) "describe[d] in detail, including the date, place, and participants, the dinner meeting at which two doctors in his section attempted to bring him into the fold of their on-going fraudulent plot," (2) "allege[d] his first-hand experience of the scheme unfolding as it

related to him, describing how the weekend on-call nursing staff attempted to assist him in recording face-to-face physician visits that had not occurred," and (3) provided "specific dates that each doctor falsely claimed to have provided services to patients and often the type of medical service or its Current Procedure Terminology code that would have been used in the bill." 565 F.3d at 191-92. The Relator has offered no details about meetings between Dr. Lewis and Medtronic and no firsthand observations as to Medtronic's involvement in decisions regarding the Relator's surgical procedure. The Relator has not provided a basis in law or fact to support her speculation about the Lewis Defendants[14] and her amended complaint is due to be dismissed under Rule 9(b).

D. Unjust Enrichment

Under Count VIII, the Relator has raised the claim that the "Defendants' conduct" constitutes unjust enrichment and that she is entitled to equitable relief. Am. Compl. ¶ 113. Under Mississippi law, the Relator must "allege and show that the defendant holds money which in equity and good conscience belongs to" her. *Owens Corning v. R.J. Reynolds Tobacco Co.*, 868 So. 2d 331, 342 (Miss. 2004) (quotation marks omitted). The Relator has not identified

[14] The Relator's speculation about the Lewis Defendants has also apparently led to a case of mistaken identity that further establishes the failed proof of the "fraudulent scheme" that she has alleged. The Relator alleged that TAZ, LLC—the Mississippi company that the Relator identified in the Secretary of State filings—was an entity that Dr. Adam Lewis had set up to receive funds from Dr. Thomas A. Zdeblick for his work with Medtronic products. The Lewis Defendants state that TAZ, LLC, was a business that Dr. Adam Lewis formed with Tommy Mills and Zoe Lewis to build and/or refurbish houses for sale; the initials T, A, Z, come from the initials of the first names of each of the company's members and have nothing to do with Thomas A. Zdeblick or TAZ Consulting. Lewis states that TAZ, LLC, never started operating because of Hurricane Katrina and the declining housing market, and states that it has no financial relationship to Medtronic and that he has never received money from them. Docket No. 85, at 3-5. Dr. Adam Lewis provides an affidavit stating the same. Docket No. 84, Exh. A. Dr. Lewis also states in his affidavit that Lewis Medical Services, PLLC has no financial or pecuniary relationship to Medtronic and it was only started to track his deductible personal expenses. *See id*. Dr. Lewis avers that Lewis Properties, LLC was set up solely to rent houses if needed and that it has no relationship to any other defendant in this action except him. The Relator has not contested the validity of this information. Thus, the Court concludes that there is no basis in fact or law to believe that the Lewis Defendants ever exchanged funds with any other Defendants through TAZ Consulting and TAZ, LLC.

what monies Medtronic holds that in "good conscience" belong to her, and it is difficult to imagine how that claim could be raised when an FCA action is premised on the defendants owing money to the government, and the relator serves as a whistleblower who notifies the government of the debt.

E. Motion to Dismiss Remaining Counts[15]

Defendants argue that Counts IV, V, VI, and VII must be dismissed because no private right of action exists for the statutes, regulations, and agreements relied upon by the Relator. These counts include violations of the AKS and the "Common Rule"[16]; violations of various criminal states and regulations, and a claim for relief based on a settlement agreement between Medtronic and the United States. At the hearing on these motions, the Relator admitted that no private right of action existed for these claims and conceded them. Accordingly, the Court also grants the motion to dismiss these claims.

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[15] In addition to joining Medtronic's lead motion to dismiss, the Dickman Defendants filed a separate motion to dismiss the amended complaint. Docket No. 66. Dickman's arguments are substantially similar to Medtronic's lead motion except with some arguments specifically about Dickman's lack of liability. Dickman also asserts that the Plaintiff has failed to state a claim on the violations of the Anti-Kickback Statute, mail fraud, wire fraud, money laundering, and the common rule statutes (Counts IV-VI), which covers the conduct of medical research on humans with federal funds, because none of these laws includes a private right of action; therefore, these claims should be dismissed. He argues that the Dickman Defendants were not parties to any of the agreements related to the breach of contract claim (Count VII), and they should be dismissed from this claim. Lastly, Dickman argues that the Relator does not have standing to bring a claim for unjust enrichment (Count VIII) on the government's behalf and has not alleged facts supporting the elements of such a claim. Aside from the response to Lewis's motion to strike the amended complaint, Docket No. 77, the Relator has provided a response to Medtronic's lead motion. *See* Docket No. 81-82. She has not provided a response specific to Dickman's motion or arguments. The Court has considered the Relator's allegations and her response to Medtronic's lead motion, *see* Docket No. 81-82, to the extent that Dickman's arguments mirror those of Medtronic's lead motions and Plaintiff has addressed them, Dickman's motion to dismiss is also granted.

[16] The "common rule" regulations, 45 C.F.R. § 46.101 *et seq.*, govern the protection of human subjects in research supported by the federal government. No private right of enforcement exists anywhere in their text or history. The Ninth Circuit, which specifically considered this question, has found that the "common rule" regulations do not confer a private right of action. *Thomas v. Catlin*, 141 F. App'x 673, 674 (9th Cir. 2005) (citing *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) ("private rights of action to enforce federal law must be created by Congress."). Congress recently considered available enforcement mechanisms for the "common rule," but did not act. *See* Research Revitalization Act of 2002, S. 3060, 107th Cong. § 501 (2002) (proposed bill was never enacted and did not provide for a private right of enforcement).

Conclusion

For the foregoing reasons, the Motion to Strike the Amended Complaint is DENIED; the Motion to Stay Proceedings is found to be MOOT; and the Motions to Dismiss the Relator's Amended Complaint (analyzed as motions for summary judgment) filed by the Defendants are GRANTED.

SO ORDERED, this the 31st day of March, 2014.

s/ Carlton W. Reeves
UNITED STATES DISTRICT JUDGE